



JFW

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Chen et al.

Serial No.: 10/701,939

Filed: November 4, 2003

For: CONTROLLED RELEASE DEPOT
FORMULATIONS

Confirmation No.: 5013

Examiner: Unknown

Group Art Unit: 1615

Attorney Docket No.: ALZ5045R1
(3139-6269US)

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

September 23, 2004
Date



Doreen Neumann
Name (Type/Print)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are not being submitted pursuant to M.P.E.P. 609 III A(2). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56 (b) exists.

U.S. Patent Documents

| <u>U.S. Patent No.</u> | <u>Publication Date</u> | <u>Patentee</u> |
|------------------------|-------------------------|-----------------|
| US - 4,443,340 | 04/17/1984 | May et al. |
| US - 4,938,763 | 07/03/1990 | Dunn et al. |
| US - 5,468,253 | 11/21/1995 | Bezwada et al. |
| US - 5,639,851 | 06/17/1997 | Bezwada et al. |
| US - 5,713,920 | 02/03/1998 | Bezwada et al. |
| US - 5,714,551 | 02/03/1998 | Bezwada et al. |
| US - 5,868,788 | 02/09/1999 | Bezwada et al. |
| US - 6,113,624 | 09/05/2000 | Bezwada et al. |

Foreign Patent Documents

| <u>Document No.</u> | <u>Publication Date</u> | <u>Patentee</u> |
|---------------------|-------------------------|-----------------|
| WO 93/24150 A | 12/09/1993 | Hutchinson |
| WO 95/13799 A | 05/26/1995 | Ramstack et al. |
| WO 00/74650 A | 12/14/2000 | Brodbeck et al. |
| WO 02/38185 A | 05/16/2002 | Dunn et al. |
| WO 02/067991 A | 09/06/2002 | Cleland et al. |
| WO 03/041684 A | 05/22/2003 | Chen et al. |
| WO 03/041685 A | 05/22/2003 | Chen et al. |
| WO 03/041757 A | 05/22/2003 | Chen et al. |
| WO 04/000269 A | 12/31/2003 | Chen et al. |
| WO 04/011054 A | 02/05/2004 | Chen et al. |

Other Documents

RAVIVARAPU, et al., "Polymer and microsphere blending to alter the release of a peptide from PLGA microspheres," European Journal of Pharmaceutics and Biopharmaceutics, Elsevier Science Publishers B.V., Amsterdam, NL, Vol. 50, No. 2, Sept. 2000.
International Search Report dated 18 May 2004 (9 pages).

Applicants offer to supply any explanation or discussion of the documents which the Examiner feels is necessary or desirable and which is requested.

This Supplemental Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits.

Respectfully submitted,



Edgar R. Cataxinos
Registration No. 39,931
Attorney for Applicants
TRASKBRITT
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: September 23, 2004

ERC/dlm:dn

Enclosures: Form PTO-1449 or PTO/SB/08
Copy of non-US documents cited

Document in ProLaw

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

2

| Complete if Known | |
|------------------------|-------------------------|
| Application Number | 10/701,939 |
| Filing Date | November 4, 2003 |
| First Named Inventor | Chen et al. |
| Group Art Unit | 1615 |
| Examiner Name | Unknown |
| Attorney Docket Number | ALZ5045R1 (3139-6269US) |

U.S. PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---------------------|-----------------------|--|--------------------------------|--|---|
| | | Number - Kind Code ² (if known) | | | |
| | | US-4,443,340 | 04/17/1984 | May et al. | |
| | | US- 4,938,763 | 07/03/1990 | Dunn et al. | |
| | | US- 5,468,253 | 11/21/1995 | Bezwada et al. | |
| | | US- 5,639,851 | 06/17/1997 | Bezwada et al. | |
| | | US- 5,713,920 | 02/03/1998 | Bezwada et al. | |
| | | US- 5,714,551 | 02/03/1998 | Bezwada et al. | |
| | | US- 5,868,788 | 02/09/1999 | Bezwada et al. | |
| | | US- 6,113,624 | 09/05/2000 | Bezwada et al. | |
| | | US- | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|---|--------------------------------|---|---|----------------|
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | | WO 93/24150 A | 12/09/1993 | Hutchinson | | |
| | | WO 95/13799 A | 05/26/1995 | Ramstack et al. | | |
| | | WO 00/74650 A | 12/14/2000 | Brodbeck et al. | | |
| | | WO 02/38185 A | 05/16/2002 | Dunn et al. | | |
| | | WO 02/067991 A | 09/06/2002 | Cleland et al. | | |
| | | WO 03/041684 A | 05/22/2003 | Chen et al. | | |
| | | WO 03/041685 A | 05/22/2003 | Chen et al. | | |
| | | WO 03/041757 A | 05/22/2003 | Chen et al. | | |
| | | WO 04/000269 A | 12/31/2003 | Chen et al. | | |
| | | WO 04/011054 A | 02/05/2004 | Chen et al. | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | |
|--|---|--------------------------|------------------|
| Substitute for form 1449A/PTO | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | Application Number | 10/701,939 |
| | | Filing Date | November 4, 2003 |
| | | First Named Inventor | Chen et al. |
| | | Group Art Unit | 1615 |
| | | Examiner Name | Unknown |
| <i>(use as many sheets as necessary)</i> | | Attorney Docket Number | |
| Sheet | 2 | of | 2 |
| | | ALZ5045R1 (3139-6269US) | |

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.